

1653

PATENT

Case Docket No. UC067.004A

Date: December 23, 2002



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Saxon
Appl. No. : 10/000,439
Filed : October 24, 2001
For : FUSION MOLECULES AND
METHODS FOR TREATMENT
OF IMMUNE DISEASES
Examiner : not yet assigned
Group Art Unit : 1653

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December 23, 2002

(Date)

Ginger R. Dreger, Reg. No. 33,055

TRANSMITTAL LETTER

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Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) A Preliminary Amendment in 5 pages.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

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UC067.004A



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PRELIMINARY AMENDMENT

United States Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Dear Sir:

Applicants respectfully request that the Preliminary Amendment provided below be entered into the record for the present case.

IN THE SPECIFICATION:

Please delete the paragraph spanning page 8, line 30 through page 9, line 7, and replace it with the following substitute paragraph:

--Tolerance therapies incorporating either parenterally and orally administered diabetes autoantigens (including insulin and GAD) have been tried in experimental models and human subjects. However, the majority of human trials have met with disappointment. Furthermore, widespread application of peptide therapy in humans to treat autoimmune diabetes has been prevented by the observation that in some cases, peptide administration may actually accelerate disease progression (Pozzilli *et al.*, *Diabetologia* 43:1000-1004 [2000]; Gale, *Lancet*

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356(9229):526-527 [2000]; Chaillous *et al.*, *Lancet* 356:545-549 [2000]; Blanas *et al.*, *Science* 274:1707-1709 [1996]; McFarland, *Science* 274(5295):2037 [1996]; and Bellmann *et al.*, *Diabetologia* 41:844-847 [1998]).--

Please delete the paragraph on page 18, spanning lines 16 through 30, and replace it with the following substitute paragraph:

--The terms "receptor comprising an immune receptor tyrosine-based inhibitory motif (ITIM)" and "ITIM-containing receptor" are used to refer to a receptor containing one or more immune receptor tyrosine-based inhibitory motifs, ITIMs. The ITIM motif can be generally represented by the formula Val/Ile-Xaa-PTyr-Xaa-Xaa-Leu/Val (where Xaa represents any amino acid). ITIM-containing receptors include, without limitation, FcγRIIb, gp49b1/gp91 (Arm *et al.*, *J. Biol. Chem.* 266:15966-73 (1991)), p91/PIR-B (Hayami *et al.*, *J. Biol. Chem.* 272:7320-7 (1997)), LIR1-3, 5, 8, LAIR-1; CD22 (van Rossenberg *et al.*, *J. Biol. Chem.*, 276(16):12967-12973 (2001)); CTL-4, CD5, p58/70/140 KIR, PIRB2-5; NKB1, Ly49 A/C/E/F/G, NKG2-A/B, APC-R, CD66, CD72, PD-1, SHPS-1, SIRP-α1, IL T1-5, MIR7, 10, hMIR(HM18), hMIR(HM9), Fas(CD95), TGFβ-R, TNF-R1, IFN-γ-R (α- and β-chains), mast cell function Ag, H2-M, HLA-DM, CD1, CD1-d, CD46, c-cbl, Pyk2/FADK2, P130 Ca rel prot, PGDF-R, LIF, LIR-R, CIS, SOCS13 and 3, as reviewed in Sinclair NR *et al.*, *supra*. Ligands for many of these receptors are also known, such as, e.g. the ligand for CD95 is called CD95 ligand, the ligands for CTLA-4 are CD80 and CD86, the ligands of IFN-γ receptor is IFN-γ, etc. Ligands for CD22 comprise the basic binding motif Nau5Ac-a(2,6)-Lac, and are discussed, for example in van Rossenberg *et al.*, 2001, *supra*.--

Please delete the paragraph spanning page 59, line 24 through page 60, line 2, and replace it with the following substitute paragraph:

--In a further specific embodiment, the two polypeptide sequences (including variants of the native sequences) are dimerized by amphiphilic helices. It is known that recurring copies of the amino acid leucine (Leu) in gene regulatory proteins can serve as teeth that "zip" two protein molecules together to provide a dimer. For further details about leucine zippers, which can serve as linkers for the purpose of the present invention, see for example: Landschulz, W. H., *et al.*